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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,470	01/11/2007	Ian Richard Matthews	006090.00023	5057

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EXAMINER	
SAEED, KAMAL A	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,470	MATTHEWS, IAN RICHARD	
	Examiner	Art Unit	
	Kamal A. Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16* is/are rejected.

7)☒ Claim(s) *1-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/06; 01/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

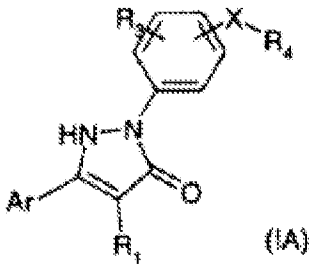
Claims 1-17 are currently pending in this application. Claim 17 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Information Disclosure Statement

Applicant's Information Disclosure Statements, filed on April 27, 2006 and January 11, 2007 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

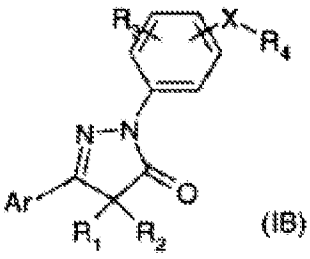
Response to Restriction

1. Applicants' election, of Group I, claims 1-16 drawn to products of Formula ,



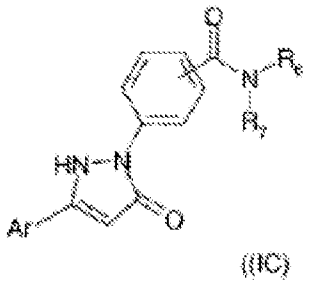
(IA)

or



(IB)

and the specific compound,



(IIC)

wherein $-C(=O)NR_6R_7$ is in the 4-position of the phenyl ring;

R_7 is hydrogen;

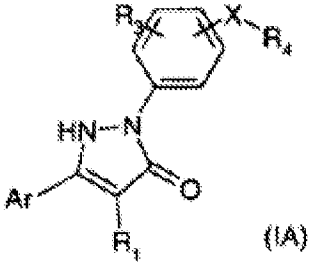
R_6 is $-AlkNR_8R_8$, wherein R_8 is Me; and

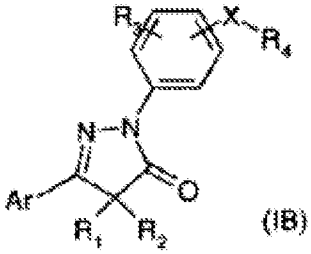
Ar is 2-furyl.

in response filed on filed on September 11, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the restriction is proper and is maintained.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The scope of the invention of the elected subject matter is as follows:


(IA)


(IB)

Compounds of Formula, or ,depicted in claim 1, wherein: **Ar** is as defined; $\mathbf{R_1}$, $\mathbf{R_2}$ and $\mathbf{R_3}$ are as defined; X is a bond; $\mathbf{R_4}$ is $-C(=O)NR_6R_7$ and $\mathbf{R_7}$ and $\mathbf{R_8}$ are as defined.

As a result of the election and the corresponding scope of the invention identified supra, claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure and function from the compounds elected. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 548 subclass 215-249(+) (oxazole), class 548 subclass 146(+) (thiazole), 548 subclass 400(+) pyrrolidines etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Nature of the Invention

Claim 16 is drawn to a medicament for the treatment of conditions which benefits from immunomodulation.

The State of the Prior Art and the Predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instantly claimed invention is highly unpredictable as discussed below: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of the above listed class of inflammatory diseases, whether or not the disease is affected by the instantly claimed compounds.

With regards to methods of treating conditions that benefit from immunomodulation, the diseases are too divergent and require different methods of treatment. Examples of disorders associated with immunomodulation include, but are not limited to: asthma, autoimmune diseases, diabetes, MS, RA, systemic lupus erythematouse or psoriasis. This broad list of diseases each has a different cause, and for the majority of the list, a different treatment. There is not one class of compounds, let alone one compound, which can treat all of these diseases. Applicant's disclosure does not enable one of ordinary skill in the art to make or use the claimed invention within the entire scope of the diseases listed above. There is no compound, let alone entire classes of compounds, that can reverse, alleviate, prolong the progression of, prevent, or treat the various and divergent diseases listed above, as claimed.

The Amount of Direction / Guidance Present and the Presence or Absence of Working Examples

The ability of the example compounds to demonstrate inhibitory effects on CD80-CD28 interaction or on the production of IL-2 is shown on pages 26-28. While it seems that assays done for the invention purport to show that compounds of Formula I tend to inhibit the CD80-CD28 interaction or the inhibition of the production of IL-2, it does not appear as though any experiments were conducted which definitely show that administration to a human patient would result in the treatment of asthma, autoimmune diseases, diabetes, MS, RA, systemic lupus erythematouse or psoriasis. *The breadth of the claims*

The claims are overbroad with regards to the claim term "immunomodulation" for the reasons stated above and "autoimmune disease" because this term is not limited to specific disease states.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the inventions is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compound exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the instant claims for the treatment of the various diseases, as a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds of the instant claims in order to practice the claimed invention. Only a majority of the claimed diseases are discussed here to make

the point of an insufficient disclosure, it does not mean that the other diseases meet the enablement requirements.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases, out of all diseases, would be benefited by the compounds and compositions of Formula i and would furthermore have to determine which of the claimed compounds would provide treatment of which disease.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that, “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to

engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

Objections

Claim 1-16 are objected to for containing non-elected subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise requires a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Kamal A Saeed/

Primary Examiner, Art Unit 1626